UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,968	06/22/2001	Thomas William Rademacher	1012E-000300	9989

22798 7590 03/06/2003

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
P O BOX 458
ALAMEDA, CA 94501

EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/06/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,968	RADEMACHER ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-43* is/are pending in the application.

4a) Of the above claim(s) *31-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 November 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election of Group I, claims 22-30, in Paper No. 7, filed Nov. 8, 2002, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 22-43 are pending.

Claims 31-43, drawn to non-elected inventions, are withdrawn from consideration.

Claims 21-30 are examined on the merits.

Claim Objections

3. Claim 22 is objected to because of the following informalities: misspelling of tumor (as tumore). Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. Claims 22-27 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The basis for this rejection is that the specification lacks adequate structural description of the genus of compounds that are encompassed by the phrases "inositolphosphoglycan

antagonist", "substance which is capable of inhibiting the release of IPGs", "substance capable of reducing the levels of IPGs by binding to the IPGs", substance which is a competitive agent which is capable of reducing an effect of IPGs", "a competitive IPG antagonist", "antibody [...] capable of neutralizing an activity of IPGs", and "inhibitor of glycosylphosphatidylinositol specific phospholipase type C".

The specification broadly contemplates IPG antagonists, but only describes three monoclonal antibodies that have IPG antagonistic activity. The specification fails to provide a descripition of which IPG activities any of the three monoclonal antibodies inhibits, and thus, while presenting examples of antagonist antibodies, fails to provide any examples of "antibodies capable of neutralizing an activity of IPGs". The antibodies described in the specification are not demonstrated to have any of the activities of the broad classes of IPG inhibitors that are recited in the claims. The specification fails to show that the antibodies inhibit the release of IPGs, that the antibodies are competitive agents with IPGs, or that the antibodies inhibit glycosylphosphatidylinositol specific phospholipase type C. Thus, the structures provided by the specification are not representative of the genus of compounds that are encompassed by the various functional limitations recited in the claims. Thus, the full scope of the claims does not appear to have been in the possession of the inventors at the time the application was filed.

5. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not set forth in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 29 is drawn to methods using the 2F7, 2D1 or 5H6 monoclonal antibody. The depository information in the specification is in adequate, because the specification lacks the address of the depository. Because claim 29 specifically requires the use of the 2F7, 2D1 or 5H6 monoclonal antibody, a suitable deposit of the hybridomas producing the 2F7, 2D1 and 5H6 monoclonal antibodies is required, or evidence must be provided that the 2F7, 2D1 and 5H6 monoclonal antibodies are well known and readily available to the public, or that they are reproducible without undue experimentation.

Applicant is required to amend the specification to recite the address of the depository. See In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 22-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Levitzki et al (U.S. Patent 5,932,580; issued Aug. 3, 1999; filed Dec. 1, 1997) as evidenced by Nazih-Sanderson et al (Biochemica et Biophysica Acta 1346: 45-60, 1997).

Claims 22-25 are drawn to methods for reducing tumor cell proliferation comprising contacting a tumor cell with an IPG antagonist having the property reducing tumor cell proliferation. The IPG antagonist may be administered in vivo to a subject. The substance may be competitive agent that reduces the effect of IPGs. The substance may be a competitive IPG antagonist.

Nazih-Sanderson teaches IPG is a mitogenic signaling mediator (page 46, 2nd col., top) that is generated upon proteolytic cleavage of GPI-anchored proteins, and that this proteolytic cleavage may be mediated by tyrosine kinases (page 58, 2nd col). Thus, an inhibitor of tyrosine kinases appear to fall within the scope of IGP antagonists.

Levitzki discloses methods for treating a proliferative disorder such as a PDGF malignancy comprising administering tyrphostins (see claims, abstract). Thus, Levitzki discloses methods that are the same as that claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varela-Nieto et al (Varela-Nieto et al, Comp. Biochem. Physiol., 115B(2): 223-241, 1996) in view of Rademacher (WO 98/11116; published 19 March 1998).

Varela-Nieto teaches that anti-IPG antibodies inhibit proliferation of cochleovestibular ganglia cells that have been stimulated by BDNF or NT-3 (page 229, 2nd col., last paragraph). Varela-Nieto also teaches that IPG is involved in growth factor signaling (see page 232-233). Thus, the prior art teaches that IPGs interact with the second messenger system of many of the growth factor receptors that are targeted in tumor therapy regimens. WO 98/11116 is cited to demonstrate that specific antibodies that inhibit IPGs are available in the prior art. Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made a method for reducing tumor cell proliferation comprising administering antibodies that bind IPGs.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
February 10, 2003